UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,014	04/11/2005	Amanda Proudfoot	ARS-103	4504

23557 7590 03/02/2007

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER	
HISSONG, BRUCE D	
ART UNIT	**PAPER NUMBER**
1646	
MAIL DATE	**DELIVERY MODE**
03/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/510,014	**Applicant(s)** PROUDFOOT ET AL.	
	Examiner Bruce D. Hissong, Ph.D.	**Art Unit** 1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 December 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): 112, first and second paragraph.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: 34.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

Continuation of 13. Other: In response to the Applicants' amendments to the claims, including cancellation of claims 13-33 and addition of new claim 34, all rejections under 35 U.S.C. 112, first and second paragraphs, are withdrawn.

Claim 34 is rejected under 35 U.S.C. 103(a), as being obvious in view of Proudfoot et al, Lusso and Polo, and Czaplewski et al, as previously applied to claims 13-33. In the response received on 12/6/2006, the Applicants argue that there is no motivation to combine these references because the references, alone or in combination, do not teach or suggest treatment of multiple sclerosis by oral administration of SEQ ID NO: 1. This argument has been fully considered and is not persuasive. As set forth in the previous office action, Czaplewski et al teaches that RANTES is involved in the pathogenesis of multiple sclerosis, and is a potential target for treatment of multiple sclerosis. Therefore, the combined references teach a polypeptide that is equivalent to SEQ ID NO: 1 (Proudfoot et al), and the usefulness of RANTES mutants for treating inflammatory diseases (Lusso and Polo), specifically multiple sclerosis (Czaplewski et al), and oral administration of RANTES mutants for treatment of disease (Czaplewski et al) Therefore, it would be obvious to a skilled artisan to orally adminster the polypeptide of SEQ ID NO: 1 to treat inflammatory disease, including multiple sclerosis. Furthermore, in regards to the Applicants' arguments that orally adminstered SEQ ID NO: 1 has unexpectedly better bioavailabity and therapeutic efficacy, it is noted that the polypeptide of Proudfoot et al, when orally adminstered, would be expected to have higher bioavailabity and therapeutic efficacy.

Claim 34 is provisionally rejected under the judicially-created doctrine of "obviousness-type" double patenting, as being unpatentably over claims 11-12, 15-16, and 19 of co-pending application 10/540/234, as previously applied to claims 13-33. In the response received on 12/6/2006, the Applicants argue that the claims of the '234 application are not obvious in view of the present application because the method of the instant application resutls in better bioavailabiity and higher efficacy of the polypeptide of SEQ ID NO: 1. This argument has been fully considered and is not persuasive. It is noted that the claims of both applications are drawn to adminstration of RANTES mutants comprising mutations in the 40's dibasic site, and administration for treatment of autoimmune disorders. Furthermore, it is also noted that the specification of the '234 application, on page 16, line 20, teaches oral administration. Thus, oral administration of the polypeptide of the '234 application would also be expected to have higher bioavailability and efficacy.

ROBERT S. LANDSMAN, PH.D
PRIMARY EXAMINER